IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Stewart, et al. Application No.: 10/683,885 Filed: 10/10/2003 Title: APPLICATOR FOR RADIATION TREATMENT OF A CAVITY Attorney Docket No.: 252/0002 Client Case no.: 667	Art Unit: 3735 Examiner: John Lacyk

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Honorable Assistant Commissioner for Patents
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APPEAL BRIEF UNDER 37 CFR 41.37

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(I) REAL PARTY IN INTEREST

The real party in interest is Xoft, Inc., the assignee of record.

(II) RELATED APPEALS AND INTERFERENCES

None.

(III) STATUS OF CLAIMS

Claims 41-50 and 53-137 are currently pending and have been rejected as being anticipated by the Lubock references (6,955,641 and 6,923,754). Claims 41-50 and 53-137 are being appealed.

(IV) STATUS OF AMENDMENTS

No Amendment has been filed subsequent to the final rejection mailed July 11, 2011. The most recently filed Response was on November 12, 2010, in response to the Non-Final Office Action mailed May 12, 2010. The response and its accompanying remarks were determined to be not persuasive, and accordingly a Notice of Appeal was filed on January 11, 2012, and this appeal brief was filed in due time with appropriate extensions.

(V) SUMMARY OF CLAIMED SUBJECT MATTER

Claim 41

Claim 41 recites an applicator for facilitating radiation treatment of a cavity inside living tissue. Refer, for example, to paragraph 0042 and Fig. 1 for support of the claim recitations. More particularly, an applicator 18, balloon 22 and flexible shaft 24 are shown in Fig. 1 and described in paragraph 0042. Also, note the surface relief means are described in paragraphs 0066-0068 and shown in corresponding Figs. 26-30. Fig. 26 shows bumps 90 as surface relief means, Fig. 27 shows grooves 92 and Figs. 28 and 29 show ridges 94 forming channels 96.

Claim 53

Claim 53 recites a device for irradiating tissue adjacent a body cavity, and contains recitations similar to the applicator of claim 41. Thus, refer to the above summary of claim 41 for a summary of claim 53. More particularly, refer, for example, to paragraph 0042 and Fig. 1 for the overall device. Also refer to paragraph 0062 describing, respectively, the service, drainage and balloon inflation ports 32, 34 and 36, shown in Fig. 23.

Claim 70

Claim 70 recites a method for irradiating tissue lining of a patient's body cavity, and contains recitations similar to the applicator of claim 41. Thus, refer to the above summary of claim 41 for a summary of claim 70.

Claim 72

Claim 72 recites a device for irradiating tissue lining defining at least in part a body cavity, and includes recitations similar to the applicator of claim 41 and the device of claim 53. Thus, refer to the above summary of claims 41 and 53 for a summary of claim 72.

Claim 89

Claim 89 recites a method for therapeutically irradiating tissue lining a patient's body cavity, and includes recitations similar to the applicator of claim 41. Thus, refer to the above summary of claim 41 for a summary of claim 89.

Claim 90

Claim 90 recites a method for therapeutically irradiating tissue a patient's body cavity, and includes recitations similar to the applicator of claim 41. Thus, refer to the above summary of claim 41 for a summary of claim 90.

Claim 91

Claim 91 recites a method for therapeutically irradiating tissue lining a patient's body cavity, and includes recitations similar to the applicator of claim 41 and the device of claim 53. Thus, refer to the above summary of claims 41 and 53 for a summary of claim 91.

Claim 99

Claim 99 recites a method for therapeutically irradiating tissue a patient's body cavity, and includes recitations similar to the applicator of claim 41. Thus, refer to the above summary of claim 41 for a summary of claim 99.

Claim 100

Claim 100 recites a method for therapeutically irradiating tissue lining a cavity within a patient's body from which tissue has been removed to necrotize residual neoplastic tissue surrounding the cavity, and includes recitations similar to the applicator of claim 41 and the device of claim 53. Thus, refer to the above summary of claims 41 and 53 for a summary of claim 100.

Claim 111

Claim 111 recites a method for therapeutically irradiating tissue lining a cavity within a patient's body from which tissue has been removed to necrotize residual neoplastic tissue surrounding the cavity, and includes recitations similar to the applicator of claim 41 and the device of claim 53. Thus, refer to the above summary of claims 41 and 53 for a summary of claim 111.

Claim 112

Claim 112 recites an elongated device for irradiating tissue forming at least in part a body cavity, and includes recitations similar to the applicator of claim 41 and the device of claim 53. Thus, refer to the above summary of claims 41 and 53 for a summary of claim 112.

Claim 135

Claim 135 recites a method for treating tissue adjacent a body cavity containing a treatment assembly, and includes recitations similar to the applicator of claim 41 and the device of claim 53. Thus, refer to the above summary of claims 41 and 53 for a summary of claim 135.

Claim 136

Claim 136 recites a device for enhancing treatment of tissue adjacent a body cavity delivered by a treatment assembly configured for delivering a treatment to tissue adjacent a body cavity, and includes recitations similar to the applicator of claim 41 and the device of claim 53. Thus, refer to the above summary of claims 41 and 53 for a summary of claim 136.

(VI) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 41-50 and 53-137 are unpatentable under §102(e) as being anticipated by the Lubock references (U.S. Pat. Nos. 6,955,641 and 6,923,754).

(VII) ARGUMENT

Rejections under 35 USC §102(e) over Lubock (U.S. Pat. Nos. 6,955,641 and 6,923,754)

Claims 41-50 and 53-137 were rejected under 35 U.S.C. §102(e) as being anticipated by Lubock (6,955,641 and 6,923,754). Inventors responded on February 22, 2011 with a declaration of prior conception under Rule 131. The Examiner rejected the declaration as insufficient, finding that a discussion of ribs dated April 30, 2003 suggests that the device was not "completed or reduced to practice" prior to the filing of the Lubock references on November 6, 2002. Applicant does not argue prior reduction to practice, but instead argues prior conception coupled with due diligence under 37 CFR 1.131(b):

> "The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, *or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application."* (emphasis added)

Conception is the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986). "The test for conception is whether the inventor had an idea that was definite and permanent enough that one skilled in the art could understand the invention." *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994). Therefore, sufficient evidence of conception presented in a declaration under Rule 131 need not show every aspect of the rejected claims, as long as those differences would be obvious to one of ordinary skill in the art. As MPEP §715.02 explains:

> "Even if applicant's 37 C.F.R. §1.131 affidavit is not fully commensurate with the rejected claim, the applicant can still overcome the rejection by showing that the differences between the claimed invention and the showing under 37 C.F.R. §1.131 would have been obvious to one of ordinary skill in the art in view of applicant's 37 C.F.R. §1.131 evidence, prior to the effective date of the reference(s) or the activity. Such evidence is sufficient because applicant's possession of what is shown carries with it possession of variations and adaptations which would have been obvious, at the same time, to one of ordinary skill in the art. However, the affidavit or declaration showing must still establish possession of the invention (i.e., the basic inventive concept) …"

Both the use of ribs on the exterior surface of an applicator balloon to create space within a body cavity, and the use of ribs in the space between an inner and outer applicator balloon were obvious to one of ordinary skill in the art at the time of conception. By way of example, this contention is supported by U.S. Pat. No. 6,099,499 and prior art reviewed by the Examiner during the prosecution of the '641 Lubock reference, specifically U.S. Pat. No. 5,106,360. Because the rib features would be obvious to one of ordinary skill in the art at the time of conception, applicant's Rule 131 declaration is sufficient.

Additionally, the facts and assertions referenced in Entry Nos. 1-3 of the declaration under Rule 131 clearly establish possession of the basic inventive concept prior to the effective filing date of the Lubock references. The declaration includes specific evidence, including Exhibit A, dated October 7, 2002, which supports the applicant's prior conception of catheters and applicators with "a drain/port/membrane […] to remove seroma." Exhibit A also clearly shows that inventors had conceived of applying "suction force." Further, inventors have declared that they conceived of drainage and all of the claims under consideration prior to the effective filing date of the Lubock references on November 6, 2002. Entry No. 2 states in part: "We conceived the invention of the claims under consideration, claims 41-50 and claims 53-137, prior to the effective filing date of Lubock Patents Nos. 6,923,754 and 6,955,641, that is prior to

November 6, 2002 [...] All balloon applicator development from prior to 11/6/02 until the filing of our patent application included the concept of drainage."

It appears that the Examiner misconstrues the meaning of the exhibits presented with applicant's Rule 131 declaration in concluding: "entry #17 clearly shows that the feature of the ribs were after the filing date of the Lubock references and therefore at least claims 41-50, 61-62, 80-81 and 121-122 would not support an earlier filing date..." This conclusion is not supported by the exhibits or the declarations. Claims 41-50, 61-62, 80-81 and 121-122 involve ribs or "surface relief means" for the purpose of facilitating drainage and for spacing tissue away from the exterior surface of the balloon. Exhibit O, dated April 30, 2003 and discussed in Entry No. 17, shows only that the inventors considered that "ribs inside the balloon could potentially control shape." The fact that ribs were discussed as a means for controlling shape, in the course of the applicant's demonstrated due diligence, does not negate prior conception of ribs. This exhibit is included in the declaration to show requisite due diligence, but is not meant to indicate the first instance that inventors considered the use of ribs. Indeed, the facts alleged in the declaration, as quoted above, directly contradict this conclusion.

The stated purpose of the "surface relief" in claims 41-50 is to facilitate drainage. The Examiner appears to have disregarded that purpose, as well as the declarations discussed above and the context of Entry No. 17, which shows only that ribs were discussed on April 30, 2003 as a means for influencing the shape of the balloons. Applicants assert that the Examiner's failure to give any probative weight to these declarations represents a reversible error, based on the holding in *Ex parte Ovshinsky*:

> "[F]ailure to give probative weight to the Rule 131 declarations constitutes reversible error. We point out to the examiner that (1) all the evidence must be considered in its

> entirety, including the Rule 131 declarations and accompanying exhibits, records and "notes", (2) an accompanying exhibit need not support all of the claimed limitations but rather a missing feature may be supplied by the declaration itself. *Ex parte Swaney*, 89 USPQ 618 (PO Bd.App. 1950), and (3) it is entirely appropriate for appellants to rely on a showing of facts set forth in the Rule 131 declarations themselves to establish conception of the invention prior to the effective date of the reference." *Ex parte Ovshinsky*, 10 U.S.P.Q.2D (BNA) 1075 (BPAI 1989).

It is believed that in considering the evidence presented in its entirety, Applicants show an effective date prior to the Lubock references. Accordingly, the rejection under 35 USC §102(e) of claims 41-50 and 53-137 is overcome and the claims are in allowable condition.

(VIII) CLAIMS APPENDIX

1. (Withdrawn) An applicator device for facilitating radiation treatment of a cavity within human tissue, comprising:

an inflatable balloon configured to be inserted into the cavity,

a lumen connected to the balloon for inflating the balloon when positioned within the cavity, and

the balloon being formed of a flexible, expandable material which includes a sufficient quantity of an x-ray-absorbing material that when inflated and inside the cavity, the balloon's peripheral edges, essentially tangential to a line of sight in an x-ray image, can be seen in such an x-ray image taken from outside the cavity.

2. (Withdrawn) The applicator device of claim 1, wherein the x-ray absorption density of the balloon wall is such as to absorb about 5% of radiation during treatment, at a selected energy level of the radiation.

3. (Withdrawn) The applicator device of claim 1, wherein the x-ray absorbing material is integrated into the flexible, expandable material of the balloon and comprises about 3% to 5% by weight barium sulfate.

4. (Withdrawn) The applicator device of claim 1, wherein the x-ray absorbent material of the balloon is sufficiently low in concentration as to absorb no more than about 5% of x-ray

radiation having an energy of about 15-40 kV at the balloon surface, when the x-ray penetrate the balloon approximately normal to the balloon surface.

5. (Withdrawn) The applicator device of claim 1, wherein the x-ray absorbing material in the balloon is of such concentration that, in an x-ray view of the balloon, the portion of the x-ray view at essentially a tangent of the balloon is a factor of about 15 to 25 times more absorbent, due to an effective path length about 15 to 25 times greater, than a portion normal to the balloon wall.

6. (Withdrawn) The applicator device of claim 1, wherein the balloon has a wall thickness which varies at different portions of the balloon, causing higher x-ray absorption in some areas than others, to control dose distribution to different areas of the tissue to be treated when x-ray radiation is delivered from within the balloon.

7. (Withdrawn) A method for determining the position of a balloon applicator placed in a cavity within human tissue, comprising:

providing an applicator device including an inflatable balloon configured to be inserted into the cavity, a lumen connected to the balloon for inflating the balloon when positioned within the cavity, and the balloon being formed of a flexible, expandable material which includes a sufficient quantity of an x-ray absorbing material that when inflated and inside the cavity, the balloon's peripheral edges, essentially tangential to a line of sight in an x-ray image, can be seen in such an x-ray image taken from outside the cavity,

inserting the applicator with the balloon into the cavity, and inflating the balloon using the lumen, and

forming an x-ray image of the inflated balloon in the cavity and detecting the position of the balloon relative to the surrounding tissues by observation of the walls of the balloon which appear in the x-ray image essentially along the tangent to the balloon wall, where x-ray absorption is maximum.

8. (Withdrawn) The method of claim 7, wherein the x-ray absorbing material in the balloon is of such concentration that, in an x-ray view of the balloon, the portion of the x-ray view at essentially a tangent of the balloon is a factor of about 15 to 25 times more absorbent than a portion normal to the balloon wall.

9. (Withdrawn) The method of claim 7, wherein the x-ray absorbing material comprises about 3% to 5% by weight barium sulfate in the balloon wall material.

10. (Withdrawn) The method of claim 7, wherein the balloon has a wall thickness which varies at different portions of the balloon, causing higher x-ray absorption in some areas than others, to control dose distribution to different areas of the tissue to be treated when x-ray radiation is delivered from within the balloon.

11. (Withdrawn) An applicator for radiation treatment of a cavity within human tissue, comprising:

an inflatable balloon insertable into the cavity in a deflated state,

a lumen connected to the balloon for inflation of the balloon following insertion into the cavity and for receiving a source of radiation inserted into the lumen,

the balloon being configured to reach a desired general shape when inflated, and

the balloon having a wall thickness which varies in different parts of the balloon so as to control the inflated shape of the balloon, thicker areas tending not to expand as extensively as thinner areas of the balloon wall.

12. (Withdrawn) The applicator of claim 11, wherein some portions of the balloon wall have a thickness which is a factor of about two times thicker than other areas of the balloon wall.

13. (Withdrawn) The applicator of claim 11, wherein the variation in balloon wall thickness is such as to restrict the expansion of thicker regions of the balloon, when the balloon is inflated, to about 70% compared to the same balloon geometry without the wall thickness variations.

14. (Withdrawn) The applicator of claim 11, wherein the balloon wall thickness variation is configured so as to produce the general shape of a football, a hotdog, a pear or a truncated cone.

15. (Withdrawn) An applicator for radiation treatment of a cavity within human tissue, comprising;

an inflatable balloon insertable into the cavity in a deflated state,

a flexible shaft connected to the balloon for inflation of the balloon following insertion into the cavity and for receiving a source of radiation,

the balloon being configured to reach a desired general shape when inflated, so as to engage a wall of the balloon against tissue surrounding the cavity, and

wherein the balloon wall has one or more ribs configured to restrict expansion along the lines of the ribs and thus to control the shape of the balloon upon inflation, to the desired general shape.

16. (Withdrawn) The applicator of claim 15, wherein the flexible shaft is arranged longitudinally relative to the balloon, and wherein at least one said rib extends circumferentially on the balloon, generally in a plane transverse to the flexible shaft.

17. (Withdrawn) The applicator of claim 15, wherein the rib or ribs are formed on the inside of the balloon wall.

18. (Withdrawn) The applicator of claim 15, wherein the rib or ribs are formed on the outside of the balloon wall.

19. (Withdrawn) The applicator of claim 15, further including a surgical drain comprising a plurality of said ribs arranged on the outside surface of the balloon so as to form channels along which seroma and other fluids from the cavity can flow in a direction toward an opening of the cavity into which the applicator has been inserted.

20. (Withdrawn) The applicator of claim 19, wherein the flexible shaft includes drain holes for withdrawing liquids from the cavity via at least one duct in the shaft and wherein the ribs are arranged to form said channels in a way to conduct liquids toward the drain holes.

21. (Withdrawn) The applicator of claim 20, wherein the flexible shaft includes at least one additional drain opening at a distal end of the flexible shaft for collecting fluids from the cavity.

22. (Withdrawn) An applicator for use in administering radiation to a cavity in living tissue, comprising:

at least two inflatable balloons positioned side by side and connected so as to be insertable into the tissue cavity together when collapsed, and a flexible shaft connected to the balloons with an inflation lumen for the balloons, at least one of the balloons having a guide within the balloon connected to a channel in the shaft for receiving a radiation source at a peripheral position in the balloon to deliver radiation to walls of the cavity.

23. (Withdrawn) The applicator of claim 22, wherein each balloon has a guide within the balloon for receiving a radiation source.

24. (Withdrawn) The applicator of claim 22, wherein the balloons are bonded together.

25. (Withdrawn) The applicator of claim 22, wherein at least three balloons are included in the applicator, secured to the flexible shaft which is located generally centrally in the applicator, and each balloon carrying a guide for receiving a source of radiation.

26. (Withdrawn) The applicator of claim 25, wherein the plurality of balloons are radially disposed around the flexible shaft and are of different sizes when inflated, whereby radiation sources can be located along the walls of an irregularly shaped cavity.

27. (Withdrawn) The applicator of claim 26, with the balloons in the cavity and inflated and with an isotope radiation source in the guide, irradiating the cavity.

28. (Withdrawn) The applicator of claim 26, the applicator including at least four balloons radially disposed around the flexible shaft, and the applicator inserted into a tissue cavity and the balloons inflated, the cavity being irregular in shape and the balloons together assuming generally the shape of the cavity and extending into irregularities.

29 . (Withdrawn) The applicator of claim 22, inserted into the tissue cavity and the balloons inflated, in combination with an isotope radiation source in the guide.

30. (Withdrawn) The applicator of claim 22, inserted into the tissue cavity and the balloons inflated, in combination with a miniature switchable x-ray tube radiation source in the guide.

31. (Withdrawn) An applicator for use in administering radiation to a cavity in living tissue, comprising;

outer and inner inflatable balloons, the inner balloon being positioned within the outer balloon and the balloons being connected and insertable into the tissue cavity when collapsed,

a shaft connected to the balloons with an inflation lumen for the balloons, and the shaft extending into the inner balloon and including a channel for receiving a radiation source to deliver radiation to walls of the cavity,

the outer wall of the inner balloon being substantially in contact with the inner wall of the outer balloon and bonded there to except at a particular desired area of the balloon where the two balloons are unbonded, and

the unbonded area between the two balloons being filled with a contrast medium to limit radiation passing through said area so as to shield cavity tissue immediately adjacent to said area.

32. (Withdrawn) An applicator for use in administering radiation to a cavity in living tissue, comprising:

an inner balloon and an outer balloon, and a flexible shaft with inflation lumens connected to the inner and outer balloons for inflation of each balloon, and

the inner balloon having a plurality of guides secured to the balloon, each guide for receiving a radiation source at a peripheral position relative to the inner balloon, to deliver radiation to walls of the cavity,

whereby expansion of both the outer balloon and the inner balloon is controllable, and whereby the positions of the guides and thus of radiation sources inserted into the guides is controllable so that radiation dose profile to the cavity can be manipulated as needed.

33. (Withdrawn) The applicator of claim 32, inserted into the tissue cavity and the balloons inflated, and further including an isotope radiation source in at least one of the guides.

34. (Withdrawn) The applicator of claim 32, inserted into the tissue cavity and the balloons inflated, and further including miniature switchable x-ray tube sources in at least some of the guides.

35. (Withdrawn) An applicator for administering radiation therapy to a surgical cavity in living tissue, comprising:

an expandable balloon for positioning within the cavity,

a flexible shaft including a lumen connected to the balloon for delivering a fluid to inflate the balloon,

the shaft being highly flexible and pliable at least in an outer or proximal portion of the shaft, positioned to be at the exterior of the cavity, so as to be foldable down adjacent to the skin of a patient during periods when radiation therapy is not being administered, and

a radially extending seal secured to the exterior of the flexible shaft, the seal being soft and pliable and being generally thin and flat and having a size and area much larger than the diameter of the flexible shaft to permit adhering of the seal to the patient's ski surrounding a

surgical opening leading to said cavity against leakage of seroma and other liquids from the wound.

36. (Withdrawn) The applicator of claim 35, wherein the seal comprises a circular disc of silicone.

37. (Withdrawn) The applicator of claim 35, wherein the seal has a central hole that fits closely over the flexible shaft, essentially sealing against the exterior of the flexible shaft but being slidable along the flexible shaft such that the seal can be moved longitudinally on the lumen for adjustment while still maintaining an essentially sealed relationship with the flexible shaft.

38. (Withdrawn) The applicator of claim 35, wherein the seal comprises a round disc having a generally radial slit extending to a central hole through which the flexible shaft passes, such that the seal can be installed onto the flexible shaft and can be interchanged.

39. (Withdrawn) The applicator of claim 35, wherein the flexible shaft includes a drain channel and at least one hole from the drain channel to the exterior of the flexible shaft, the holes being positioned to be inside the patient's tissue for withdrawal of liquids from the cavity as retained therein by the seal.

40. (Withdrawn) The applicator of claim 39, with the flexible shaft folded down at the exterior of the cavity, adjacent to the skin of the patient, the drain channel being effective to drain liquids from the cavity while the tube device is folded down.

41. (Original) An applicator for facilitating radiation treatment of a cavity inside living tissue, comprising:

an inflatable balloon having a collapsed state and an inflated state,

a flexible shaft secured to the balloon and being elongated so as to extend from inside the surgical cavity to outside the surgical cavity when installed, said flexible shaft having a lumen for introducing a fluid to the balloon to inflate the balloon,

surface relief means on the exterior of the balloon for providing channels when the balloon is inflated, to allow the flow of liquids from the surgical cavity toward the exit of the surgical cavity, and

at least one drain channel provided in the flexible shaft, positioned to receive draining liquids from the surgical cavity, and means in the flexible shaft for conducting said liquids out of the surgical cavity through the drain channel.

42. (Original) The applicator of claim 41, wherein the flexible shaft has a central longitudinal channel and a series of outer longitudinal channels arranged generally in an annular array around the central longitudinal channel, at least one of the outer channels comprising said drain channel and being open at a distal end of the flexible shaft to collect liquid.

43. (Original) The applicator of claim 42, wherein the flexible shaft has entry holes proximal of the balloon, communicating with at least one drain channel, providing another location to collect drain liquids.

44. (Original) The applicator of claim 41, wherein a proximal end of the flexible shaft is branched, one branch having said drain channel and adapted to an aspirator to draw off liquids, another branch having said lumen for inflation of the balloon, and a further branch having a channel for insertion of a radiation delivering source, through said central longitudinal channel.

45. (Original) The applicator of claim 44, wherein said lumen comprises one of the outer channels.

46. (Original) The applicator of claim 44, wherein the balloon includes guides to receive the radiation delivery source, said guides connected to said central longitudinal channel and said further branch.

47. (Original) The applicator of claim 41, wherein the surface relief means comprises longitudinally extending ridges on the exterior of the balloon, providing channels between adjacent ridges.

48. (Original) The applicator of claim 47, wherein the ridges are interrupted in their length, providing for cross flow of liquids between channels.

49. (Original) The applicator of claim 41, wherein the surface relief means comprises bumps extending outwardly on the exterior of the balloon.

50. (Original) The applicator of claim 41, wherein the surface relief means comprises grooves extending inwardly on the exterior surface of the balloon.

51. (Withdrawn) An applicator device for facilitating radiation treatment of a cavity within human tissue, comprising:

an inflatable balloon configured to be inserted into the cavity when uninflated,

a flexible shaft connected to the balloon for inflating the balloon when positioned within the cavity, and

the flexible shaft having a stiffener on a portion of the shaft within the balloon, the stiffener comprising a sleeve tightly engaging over the other surface of the flexible shaft.

52. (Withdrawn) The applicator of claim 51, wherein the stiffener comprises a heat shrink material over the shaft within the balloon.

53. (Previously Presented) A device for irradiating tissue adjacent a body cavity, comprising:

a. an elongated shaft having a proximal shaft section, a distal shaft section, a first lumen extending through the proximal shaft section and into the distal shaft section for receiving and advancing an irradiation source to an irradiation location in the distal shaft section;

b. at least one vacuum port in the distal shaft section which is configured to directly open to and be in fluid communication with the body cavity and at least one vacuum lumen extending to and in fluid communication with the at least one vacuum port; and

c. a single expandable member which surrounds the irradiation location on the distal shaft section, which has a first configuration for passage to the body cavity and which has a second expanded configuration with larger transverse dimensions than the first configuration to receive the tissue lining of the body cavity upon the application of a vacuum to the body cavity through the vacuum port and to shape the body cavity to the expanded expandable member in order to effectively receive therapeutic irradiation.

54. (Previously Presented) The device of claim 53, wherein at least one vacuum port is proximal to the expandable member.

55. (Previously Presented) The device of claim 53, wherein at least one vacuum port is distal to the expandable member.

56. (Previously Presented) The device of claim 53, wherein at least one vacuum port is proximal to the expandable member and at least one vacuum port is distal to the expandable member.

57. (Previously Presented) The device of claim 53, wherein at least one vacuum lumen is in fluid communication with the at least one vacuum port proximal to the expandable member.

58. (Previously Presented) The device of claim 53, wherein at least one vacuum lumen is in fluid communication with the at least one vacuum port distal to the expandable member.

59. (Previously Presented) The device of claim 53, wherein the expandable member is an inflatable balloon with an interior configured to receive inflation fluid.

60. (Previously Presented) The device of claim 59, wherein the shaft has an inflation lumen which extends through the proximal shaft section to the distal shaft section and which is in fluid communication with the interior of the balloon.

61. (Previously Presented) The device of claim 59, wherein the inflatable balloon has at least one rib on the exterior thereof.

62. (Previously Presented) The device of claim 61, wherein the rib is configured to space at least part of the tissue adjacent the cavity away from an exterior surface of the balloon.

63. (Previously Presented) The device of claim 59, wherein the balloon is formed at least in part of a flexible material.

64. (Previously Presented) The device of claim 63, wherein the flexible material is formed at least in part of a polymeric material.

65. (Previously Presented) The device of claim 64, wherein the polymeric material is a biocompatible polymer.

66. (Previously Presented) The device of claim 64, wherein the polymeric material is at least in part radiation-resistant.

67. (Previously Presented) The device of claim 64, wherein the polymeric material is selected from the group consisting of a polyolefin, polyethylene, polypropylene, polyurethane, polyester, polyvinylchloride, polystyrene, nylon, latex rubber, silicon rubber and a thermoplastic polymer.

68. (Previously Presented) The device of claim 59, wherein the balloon is formed at least in part of an elastic material.

69. (Previously Presented) The device of claim 59, wherein the balloon is formed at least in part of an inelastic material.

70. (Previously Presented) A method for irradiating tissue lining of a patient's body cavity, comprising:

a. providing an irradiation device which has an elongated shaft, an expandable member on a distal portion of the shaft and an interior within the expandable member configured to receive an irradiation source;

b. advancing the irradiation device within the patient until the expandable member thereof is disposed within the body cavity;

c. expanding the expandable member within the body cavity to a desired expanded configuration;

d. conforming the tissue lining of the body cavity about the expanded configuration of the expandable member by applying a vacuum to an exterior region about the expandable member through the vacuum port and;

e. introducing an irradiating source into the interior of the expandable member at an irradiation site; and

f. irradiating the conforming tissue lining of the body cavity about the expanded shape of the expandable member by the irradiating source within the interior of the expandable member.

71. (Previously Presented) The method of claim 70, wherein irradiating source is a radioactive material.

72. (Previously Presented) A device for irradiating a tissue lining defining at least in part a body cavity, comprising:

a. an elongated shaft having a proximal shaft section, a distal shaft section and an irradiation location in the distal shaft section;

b. at least one vacuum port in the distal shaft section configured to directly open to and be in fluid communication with the body cavity and at least one vacuum lumen extending to and in fluid communication with the at least one vacuum port in the distal shaft section; and

c. A single expandable member which surrounds the irradiation location on the distal shaft section, which has a first configuration for passage to the body cavity and which has a second expanded configuration of predetermined shape with larger transverse dimensions than the first configuration to receive the tissue lining of the body cavity upon the application of a vacuum to the body cavity through the vacuum port and to thereby shape the body cavity to receive therapeutic irradiation.

73. (Previously Presented). The device of claim 72, wherein at least one vacuum port is proximal to the expandable member.

74. (Previously Presented) The device of claim 72, wherein at least one vacuum port is distal to the expandable member.

75. (Previously Presented) The device of claim 72, wherein at least one vacuum port is proximal to the expandable member and at least one vacuum port is distal to the expandable member.

76. (Previously Presented) The device of claim 72, wherein at least one vacuum lumen is in fluid communication with the at least one vacuum port proximal to the expandable member.

77. (Previously Presented) The device of claim 72, wherein at least one vacuum lumen is in fluid communication with the at least one vacuum port distal to the expandable member.

78. (Previously Presented) The device of claim 72, wherein the expandable member is an inflatable balloon with an interior configured to receive inflation fluid.

79. (Previously Presented) The device of claim 72, wherein the shaft has an inflation lumen which extends through the proximal shaft section to the distal shaft section and which is in fluid communication with the interior of the balloon.

80. (Previously Presented) The device of claim 72, wherein the inflatable balloon has at least one rib on the exterior thereof.

81. (Previously Presented) The device of claim 80, wherein the rib is configured to space at least part of the tissue adjacent the cavity away from an exterior surface of the balloon.

82. (Previously Presented) The device of claim 78, wherein the balloon is formed at least in part of a flexible material.

83. (Previously Presented) The device of claim 78, wherein the balloon is formed at least in part of an elastic material.

84. (Previously Presented) The device of claim 79, wherein the balloon is formed at least in part of an inelastic material.

85. (Previously Presented) The device of claim 72, wherein the flexible material is formed at least in part of a polymeric material.

86. (Previously Presented) The device of claim 85, wherein the polymeric material is a biocompatible polymer.

87. (Previously Presented) The device of claim 85, wherein the polymeric material is at least in part radiation-resistant.

88. (Previously Presented) The device of claim 85, wherein the polymeric material is selected from the group consisting of a polyolefin, polyethylene, polypropylene, polyurethane, polyester, polyvinylchloride, polystyrene, nylon, latex rubber, silicon rubber and a thermoplastic polymer.

89. (Previously Presented) A method for therapeutically irradiating tissue lining a patient's body cavity, comprising:

a. providing an irradiation device which has an elongated shaft, an expandable member on a distal portion of the shaft with a first configuration for delivery and a second configuration

with an exterior of desired shape having larger transverse dimensions than the first configuration and an inner lumen extending through the elongated shaft leading to an irradiation location within the expandable member;

b. advancing the irradiation device within the patient with the expandable member in the first configuration until the expandable member thereof is disposed within the body cavity;

c. expanding the expandable member within the body cavity to a second configuration;

d. conforming the tissue lining the body cavity to the exterior of the expandable member in the second configuration within the body cavity; and

e. irradiating tissue conforming to the exterior of the expandable member by an irradiating source disposed in the irradiation location within the interior of the expandable member in the second configuration.

90. (Previously Presented) A method for therapeutically irradiating tissue a patient's body cavity, comprising:

a. the step for providing an irradiation device which has an elongated shaft, an expandable member on a distal portion of the shaft with a first configuration for delivery and a second configuration with an exterior of desired shape having larger transverse dimensions than the first configuration and an inner lumen extending through the elongated shaft leading to an irradiation location within the expandable member;

b. the step for advancing the irradiation device within the patient with the expandable member in the first configuration until the expandable member thereof is disposed within the body cavity;

c. the step for expanding the expandable member within the body cavity to a second configuration;

d. the step for conforming the tissue lining the body cavity to the exterior of the expandable member in the second configuration within the body cavity; and

e. the step for irradiating tissue conforming to the exterior of the expandable member by an irradiating source disposed at the irradiation location within the interior of the expandable member in the second configuration.

91. (Previously Presented) A method for therapeutically irradiating tissue lining a patient's body cavity, comprising:

a. providing an irradiation device which has an expandable member with a first configuration for delivery, a second expanded configuration with an exterior of desired shape having larger transverse dimensions than the first configuration and an interior;

b. disposing the irradiation device within the patient's body cavity with the expandable member in the first configuration;

c. expanding the expandable member within the patient's body cavity to the second configuration;

d. applying a vacuum to the patient's body cavity to conform tissue lining the body cavity to the exterior of the expanded expandable member in the second configuration; and

e. irradiating tissue conforming to the exterior of the expandable member by an irradiating source disposed within the interior of the expandable member in the second configuration.

92. (Previously Presented) The method of claim 91, wherein the expandable member is contracted within the body cavity and removed from the cavity.

93. (Previously Presented) The method of claim 91, wherein the irradiating source is radioactive.

94. (Previously Presented) The method of claim 91, wherein the irradiation device has an elongated shaft which extends out of the patient's body cavity when the expandable member is deployed within the patient's body cavity.

95. (Previously Presented) The method of claim 94, wherein the elongated shaft has an inner lumen extending therein which is in fluid communication with a port in a distal portion of the irradiation device.

96. (Previously Presented) The method of claim 95, wherein the port is distal to the expandable member.

97. (Previously Presented) The method of claim 95, wherein the port is proximal to the expandable member.

98. (Previously Presented) The method of claim 95, wherein vacuum is applied to the body cavity through the inner lumen of the shaft.

99. (Previously Presented) A method for therapeutically irradiating tissue a patient's body cavity, comprising:

a. the step for providing an irradiation device which has an expandable member with a first configuration for delivery, a second expanded configuration with an exterior of desired shape having larger transverse dimensions than the first configuration and an interior;

b. the step for disposing the irradiation device within the patient's body cavity with the expandable member in the first configuration.

c. the step for expanding the expandable member within the patient's body cavity to the second configuration.

d. the step for applying a vacuum to the patient's body cavity to conform tissue lining the body cavity to the exterior of the expanded expandable member in the second configuration; and

e. the step for irradiating tissue conforming to the exterior of the expandable member by an irradiating source disposed within the interior of the expandable member in the second configuration.

100. (Previously Presented) A method for therapeutically irradiating tissue lining a cavity within a patient's body from which tissue has been removed to necrotize residual neoplastic tissue surrounding the cavity, comprising:

a. expanding an expandable member with an exterior surface within the cavity to a configuration having transverse dimensions less than maximum transverse dimensions of the body cavity,

b. applying a vacuum to the patient's body cavity to conform tissue lining the body cavity to the exterior surface of the expanded expandable member, and

c. irradiating tissue conforming to the exterior of the expandable member by an irradiating source within the interior of the expandable member in the expanded configuration.

101. (Previously Presented) The method of claim 100, wherein the irradiating source is a radioactive material.

102. (Previously Presented) The method of claim 101, wherein the radioactive source has a shape that is different than the shape of the expanded expandable member.

103. (Previously Presented) The method of claim 102, wherein the expanded expandable member has a spherical shape.

104. (Previously Presented) The method of claim 103, wherein the radioactive source has a cylindrical shape.

105. (Previously Presented) The method of claim 100,wherein the tissue conforming to the exterior surface of the expanded expandable member is irradiated by a radioactive source for a preselected time period.

106. (Previously Presented) The method of claim 100, wherein the expanded expandable member is contracted within the body cavity and removed from the cavity after tissue lining the body cavity has been irradiated by the radioactive source for a preselected time period.

107. (Previously Presented) The method of claim 100, wherein the irradiating source is radioactive.

108. (Previously Presented) The method of claim 100, wherein the expandable member has a delivery configuration that has smaller transverse dimensions than the expanded configuration.

109. (Previously Presented) The method £0 claim 108, wherein the expandable member is advanced into the body cavity in the delivery configuration.

110. (Previously Presented) The method of claim 100, wherein the expandable member is an inflatable balloon.

111. (Previously Presented) A method for therapeutically irradiating tissue lining a cavity within a patient's body from which tissue has been removed to necrotize residual neoplastic tissue surrounding the cavity, comprising:

a. the step for expanding an expandable member with an exterior surface within the cavity to a configuration having transverse dimensions less than maximum transverse dimensions of the body cavity,

b. the step for applying a vacuum to the patient's body cavity to conform tissue lining the body cavity to the exterior surface of the expanded expandable member, and

c. the step for irradiating tissue conforming to the exterior of the expandable member by an irradiating source within the interior of the expandable member in the expanded configuration.

112. (Previously Presented) An elongated device for irradiating tissue forming at least in part a body cavity, comprising:

a. an elongated shaft having a proximal shaft section, a distal shaft section and an irradiation location in the distal shaft section;

b. a treatment member which surrounds the irradiation location on the distal shaft section and which is configured for deployment within the body cavity; and

c. at least one vacuum port in a distal portion of the device proximal or distal to the treatment member which is configured to directly open to and be in fluid communication with the body cavity and a vacuum lumen leading to the vacuum port to develop a vacuum within the body cavity to conform the body cavity to the treatment member in order to deliver an effective dose of therapeutic irradiation from a radiation source at the irradiation location to tissue forming the body cavity.

113. (Previously Presented) The device of claim 112, wherein at least one vacuum port is proximal to the treatment member.

114. (Previously Presented) The device of claim 112 wherein at least one vacuum port is distal to the treatment member.

115. (Previously Presented) The device of claim 112 wherein at least one vacuum port is proximal to the treatment member and at least one vacuum port is distal to the treatment member.

116. (Previously Presented) The device of claim 113 wherein at least one vacuum lumen is in fluid communication with the at least one vacuum port proximal to the treatment member.

117. (Previously Presented) The device of claim 114, wherein at least one vacuum lumen is in fluid communication with the at least one vacuum port distal to the treatment member.

118. (Previously Presented) The device of claim 112, wherein the treatment member is expandable.

119. (Previously Presented) The device of claim 118, wherein the expandable treatment member is an inflatable balloon with an interior configured to receive inflation fluid.

120. (Previously Presented) The device of claim 119, wherein the shaft has an inflation lumen which extends through the proximal shaft section to the distal shaft section and which is in fluid communication with the interior of the balloon.

121. (Previously Presented) The device of claim 119, wherein the inflatable balloon has at least one rib on the exterior thereof.

122. (Previously Presented) The device of claim 121, wherein the at least one rib is configured to space at least part of the tissue adjacent the cavity away from an exterior surface of the balloon.

123. (Previously Presented) The device of claim 119, wherein the balloon is formed at least in part of a polymeric material.

124. (Previously Presented) The device of claim 123, wherein the polymeric material is flexible material.

125. (Previously Presented) The device of claim 123, wherein the polymeric material is elastic material.

126. (Previously Presented) The device of claim 123, wherein the polymeric material is inelastic material.

127. (Previously Presented) The device of claim 123, wherein the polymeric material is a biocompatible polymer.

128. (Previously Presented) The device of claim 123, wherein the polymeric material is at least part radiationresistant.

129. (Previously Presented) The device of claim 123, wherein the polymeric material is selected from the group consisting of a polyolefin, polyethylene, polypropylene, polyurethane, polyester, polyvinylchloride, polystyrene, nylon, latex rubber, silicon rubber and a thermoplastic polymer.

130. (Previously Presented) The device of claim 123, wherein the polymeric material is polyester.

131. (Previously Presented) The device of claim 123, wherein the polymeric material is nylon.

132. (Previously Presented) The device of claim 123, wherein the polymeric material is a thermoplastic polymer.

133. (Previously Presented) The device of claim 112, wherein the treatment member has a spherical shape.

134. (Previously Presented) The device of claim 119, wherein the balloon has a spherical shape in an inflated balloon.

135. (Previously Presented) A method for treating tissue adjacent a body cavity containing a treatment assembly, comprising:

deploying said treatment assembly within the body cavity, and

applying a vacuum to said body cavity effective to draw said tissue adjacent the body cavity towards said treatment assembly and treating said tissue using the treatment assembly.

136. (Previously Presented) A device for enhancing treatment of tissue adjacent a body cavity delivered by a treatment assembly configured for delivering a treatment to tissue adjacent a body cavity, comprising:

an enclosure device configured to at least partly enclose said treatment assembly for delivering a treatment to body tissue adjacent a body cavity;

a vacuum conduit and a vacuum source connected to the vacuum conduit at a proximal end of the conduit; and

a vacuum port operatively connected to said vacuum conduit configured to provide suction adjacent to said enclosure device and within said body cavity.

137. (Currently Amended) The device for enhancing treatment of tissue of claim 136, wherein said enclosure device comprises an inflatable balloon.

(IX) EVIDENCE APPENDIX

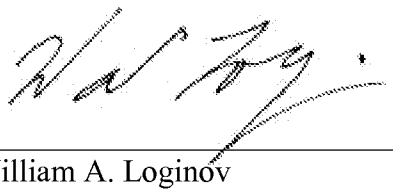
None.

(X) RELATED PROCEEDINGS APPENDIX

None.

Should any unresolved issues remain that require, it is respectfully requested that the undersigned attorney for applicant be telephoned at 603-336-3026 so that such issues may be resolved as expeditiously as possible. Please charge any fee or fee deficiency that is otherwise unpaid to Deposit Account Number 504479.

Respectfully Submitted,



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